

REMARKS

In response to the Office action mailed March 10, 2011, Applicants have amended claim 20 to promote clarity. Support for this amendment can be found, e.g., at page 22, line 12 of the specification. Applicants have also corrected typographical errors in claims 1-3, 6, 15, 17 and 24, and the specification. No new matter has been introduced by above the amendments. Claims 1-6 and 16-26 are presented for examination.

Claim 24 is rejected under 35 U.S.C. §112, 2nd paragraph as indefinite. Applicants have amended this claim to obviate this rejection.

Claims 1-6 and 16-26 are rejected under 35 U.S.C. §102(b) as anticipated by, or under 35 U.S.C. §103(a) as obvious from, Shimagaki et al., U.S. Patent No. 6,103,117 ("Shimagaki").

Independent claim 1 is discussed first. Claim 1 recites a polysulfone permselective hollow fiber membrane bundle that contains poly(vinylpyrrolidone). The membrane bundle shows a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the hollow fiber membrane when measured according to the procedure recited in claim 1.

Shimagaki does not explicitly disclose a membrane bundle that exhibits a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the hollow fiber membrane when measured according to the procedure recited in claim 1.¹ Further, the Examiner has not provided any evidence or rationale that the membrane bundles disclosed in Shimagaki *necessarily* exhibit the hydrogen peroxide-eluting amount recited in claim 1.² In addition, there would have been no reason for one skilled in the art to have modified Shimagaki to obtain the membrane bundle recited in claim 1.

Specifically, as an example, Shimagaki discloses heating the components for manufacturing a hollow fiber membrane bundle to 80-90°C for 12 hours to dissolve them in a solvent and form a membrane stock solution. *See* Examples 1-11. Shimagaki does not disclose kneading its components before dissolution or dissolving components under an inert gas. By

¹ Note that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See* MPEP 2131.

² A finding that a feature is "inherent" in a prior art reference requires that the feature is *necessarily* present in the reference. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *See* MPEP 2112IV, emphasis added.

contrast, the present specification teaches dissolving the components for manufacturing a membrane bundle in a solvent at a temperature between 5-70°C for about 1-3 hour in an inert gas. See paragraphs [0033] and [0034], and Examples 1-4. Further, the present specification teaches kneading the components before dissolving them in a solvent. *Id.* Given that the manufacturing process disclosed in Shimagaki heats the membrane components at a relative high temperature for a relatively long period of time to dissolve them in a solvent, it would have been apparent to one skilled in the art that the manufacturing process disclosed in Shimagaki would not produce a membrane bundle that exhibits the hydrogen peroxide-eluting amount recited in claim 1. Indeed, according to the specification of the present application:

when the spinning solution comprising a polysulfone polymer, poly(vinylpyrrolidone) and a solvent is stirred and dissolved, and if the poly(vinylpyrrolidone) contains hydrogen peroxide, hydrogen peroxide is explosively increased in amount because of the influence of oxygen in a dissolution tank and the influence of heating for the dissolution of the spinning solution. Therefore, it is preferable to feed raw materials into a dissolution tank whose atmosphere is previously replaced with an inert gas.

...

As another method to inhibit the genera[t]ion of hydrogen peroxide, it is also important to dissolve a membrane-forming solution in shorter time.

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To overcome this problem, the present inventors have tried to blend raw materials at a lower temperature in order to inhibit the decomposition of poly(vinylpyrrolidone). The dissolution of the raw materials at a temperature of as extremely low as a freezing point requires a high running cost. Therefore, the temperature is usually from 5 to 70°C, preferably 60°C or lower. However, a simple measure to lower the dissolving temperature requires a longer dissolving time which may induce the deterioration/decomposition of poly(vinylpyrrolidone) and a lower efficiency of the operation and requires a large-scale apparatus.

...

As a result of the present inventors' extensive trials to dissolve poly(vinylpyrrolidone) at a lower temperature and in shorter time, they have found out that it is preferable to previously knead the components of a spinning solution prior to the dissolution thereof, followed by dissolving them.

See paragraphs [0032]-[0034]; emphases added. In sum, to form a membrane bundle that exhibits a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the

hollow fiber membrane, the specification teaches, among other things, dissolving the components for manufacturing the membrane bundles in a solvent at a relatively low temperature (*e.g.*, between 5-70°C) for a relatively short period of time (*e.g.*, about 1-3 hours) in an inert gas. In addition, to reduce the time it takes to dissolve the components in a solvent at a relative low temperature, the specification teaches kneading the components prior to dissolving them in the solvent. Shimagaki is completely silent on these measures. Thus, in view of the teachings in the present specification, it would have been apparent to one skilled in the art that the manufacturing methods described in Shimagaki (*i.e.*, dissolving its components at 80-90°C in air without prior kneading) would result in membrane bundles containing a large amount of hydrogen oxide, which in turn would exhibit a hydrogen peroxide-eluting amount more than 5 ppm with respect to the mass of the hollow fiber membrane, as recited in claim 1. Thus, claim 1 is not anticipated or rendered obvious by Shimagaki.

The Examiner asserts in the Office action that

Arguments are not commensurate in scope with the claims, because the claims do not recite the argued details for making the membrane that would result in the applicant's stated less than 5 ppm peroxide. However, even if included, such process limitations would not overcome the *prima facie* case of anticipation/obviousness without secondary evidence that the reference product do not exhibit the claimed features of elution of peroxide.

See the paragraph bridging pages 5-6. Applicants disagree. First, Applicants would like to bring to the Examiner's attention that claim 19 recites kneading at least the poly(vinylpyrrolidone) in an inert gas before dissolving the poly(vinylpyrrolidone) in a solvent and claim 20 recites dissolving the poly(vinylpyrrolidone) in a solvent in an inert gas at 5-70°C to form a solution. Thus, contrary to the Examiner's assertion, the pending claims recite the steps for making a membrane bundle that exhibits a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the hollow fiber membrane. Given that Shimagaki does not disclose the processes recited in claims 19 and 20, these two claims are clearly not anticipated or rendered obvious by Shimagaki.

In addition, Applicants have provided the secondary evidence above (*i.e.*, the disclosure in Shimagaki regarding dissolving the components at 80-90°C in air without prior kneading) showing that the membrane bundle disclosed in Shimagaki would not exhibit the hydrogen

peroxide-eluting amount recited in claim 1. Thus, Applicants submit that claim 1 is not rendered obvious by Shimagaki on this ground.

The Examiner also asserts that "one of ordinary skill in the art would only consider using the purest form of materials available in the market for making such membranes because they are intended for medical applications." *See* the Office action, page 6, last sentence. As discussed above, Shimagaki discloses heating the components for manufacturing a hollow fiber membrane bundle at a relative high temperature (*i.e.*, 80-90°C) for a relatively long period of time (*i.e.*, 12 hours) to dissolve them in a solvent and form a membrane stock solution. As also discussed above, Shimagaki does not disclose kneading its components before dissolving them in a solvent or dissolving components under an inert gas. In contrast, the present specification teaches that the amount of hydrogen peroxide in such a manufacturing process would be increased significantly. Thus, even if one skilled in the art uses relatively pure starting materials in the manufacturing process used in Shimagaki, the process would still produce a membrane bundle containing a higher amount of hydrogen peroxide than that recited in claim 1.

For at least the reasons set forth above, claim 1 is not anticipated or rendered obvious by Shimagaki. Since claim 2-6 and 16-26 depend from claim 1, they also are not anticipated or rendered obvious by Shimagaki.

Applicants submit that this application is now in condition for allowance, an action of which is respectfully requested.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; (b) made arguments for the patentability of some claims does not mean that there are no other good reasons for the patentability of those claims and other claims; or (c) amended a claim does not mean that Applicants concede any of the Examiner's positions with respect to that claim or other claims.

The \$1,110.00 fee for the Petition for Three-Month Extension of Time is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization.

Applicant : Kimihiro Mabuchi et al.
Serial No. : 10/599,167
Filed : September 21, 2006
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Attorney's Docket No.: 19461-0006US1 / 548063

Please apply any other charges to Deposit Account 06-1050, referencing Attorney's
Docket No. 19461-0006US1. Respectfully submitted,

Date: September 7, 2011

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